UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,387	08/01/2000	Patrick Soon-Shiong	ABI1150-18	5713

30542 7590 08/10/2004

FOLEY & LARDNER
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/628,387	SOON-SHIONG ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,12-16,58-60,74-78,128-131 and 145-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,12-16,58-60,74-78,128-131 and 145-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The request for the extension of time, amendment and the terminal disclaimer filed on 2-10-04 and the request for the extension of time and the terminal disclaimer filed on 3-5-04 are acknowledged.

Claims included in the prosecution are 1-3, 12-16, 58-60, 74-78, 128-131, and 145-147.

In view of the terminal disclaimers, the double patenting rejections are withdrawn.

Claim Rejections - 35 USC 112

The following is a quotation of the-first paragraph 0f 35 U.S.C. I 12:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 remain rejected under 35 U.S.C. 1 12, first paragraph, as based on a disclosure which is not enabling. Elements which are critical or essential to the practice of the invention, but not included in the claims) are not enabled by the disclosure. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). This was set forth in the previous action.Applicant's arguments have been fully considered, but are not found to be persuasive. A detailed action was set forth in the previous action as to why this rejection was made. Applicant's only response is that the support for the

preparation of unit dosage forms of cremophor-free paclitaxel beginning on page 10 and provides exemplary procedures for the preparation of unit dosage of cremophor-free paclitaxel in Example 12. This argument is not found to be persuasive since as pointed out in the previous action, the rejection is made on the basis that certain critical elements are not recited in the claims. The rejection is maintained.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-3, 12-16, 58-60, 74-78, 128-131 and 145-147 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-89 of U.S. Patent No. 6,506,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because paclitaxel and docetaxel recited in the patented composition and method of administration claims (claims 1 and 63 for example) are deemed to be

included in taxane recited in instant claims. Both the patented claims and pending claims recite the same amounts of the compounds.

3. Claims 1-3, 12-16, 58-60, 74-78, 128-131, and 145-147 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,753,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because paclitaxel recited in the patented claims is deemed to be included in taxane recited in instant claims. Both the patented claims and pending claims recite the same amounts of the compounds. Docetaxel and paclitaxel analog recited in instant claims are obvious variants of paclitaxel. Instant method claims recite the same limitations as the composition claims without reciting any specific administration steps and therefore, it is deemed obvious over the patented claims since the patented claims recite the intended limitation, 'for administration to a human'.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 12-14, 58, 74-76, 128-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Catalog (1992).

Instant claims are drawn to 'a unit dosage form comprising a sealed vial containing a sufficient quantity of cremophor-free taxane". No specific amounts in terms of either milligrams or grams are recited in the claims. The only limitation in the claim is the functional limitation. Since the amounts expressed in mg/m2 depend on the size of the individual, instant claims can include any amount of the compound.

Claims are given broadest reasonable interpretation. In instant case, Sigma catalog which discloses Taxol (cremophor-free) in amounts of 1 mg, 5 mg and 25 mg quantities meets the requirements of the claims (see page 938). Since products by biochemical companies are generally sold in sealed vials or containers, such teaching is implicit.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 12-14, 58-60, 74-76 and 128-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigma catalog cited above by itself or in combination with 1994 edition of Drug Facts and Comparisons pages 2780-2785, 3558 of record.

As pointed out above, Sigma catalog indicates that Taxol is available for sale. Since the amount in a sealed container depends upon how much quantity is requested and how much is needed for a particular study whether it is for clinical purposes or cancer research purposes, it is deemed obvious to one of ordinary skill in the art that one can custom request larger amounts in a specific desired form from companies, if desired.

As pointed out in the earlier actions, Drugs, Facts and Comparisons teaches that on December 29, 1992, the FDA approved paclitaxel for treatment. Further, the reference shows that the formulations, which were approved, are 135 mg/m2 or 175 mg/m 2, administered intravenously over three hours every three weeks. It would appear that the paclitaxel formulations recited in this reference are in cremophor (polyoxyethoxylated castor oil) and dehydrated alcohol for stability, in amounts of 30 mg/5ml. It would have been obvious to one of ordinary skill in the art to prepare Taxol formulations without cremophor if this excipient is not suitable for the human condition treated. To prepare the desired amounts of the formulations in sealed containers is well within the highly developed art of medical sciences. The examiner cites in this context, the routine use in hospitals, of intravenous solutions of saline or dextrose in sealed units. One of ordinary skill in the art would be further motivated to use Taxol without cremophor and use in a desired formulation, since Sigma catalog shows the availability of Taxol in pure form without additives.

5. Claims 1-3, 12-16, 58-60, 74-78, 128-131, and 145-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1994 edition of Drug Facts and

Comparisons pages 2780-2785, 3558 or Straubinger (5,415,869) by themselves or in combination.

As pointed out above, Drugs, Facts and Comparisons teaches that on December 29, 1992, the FDA approved paclitaxel for treatment. Further, the reference shows that the formulations, which were approved, are 135 mg/m2 or 175 mg/m 2, administered intravenously over three hours every three weeks. The reference also teaches docetaxel. It would appear that the paclitaxel formulations recited in this reference are in cremophor (polyoxyethoxylated castor oil) and dehydrated alcohol for stability, in amounts of 30 mg/5ml.

Straubinger while disclosing several taxane formulations teaches that cremophor when used as vehicle has been shown to cause fatal hypersensitivity episodes and therefore advocates alternate vehicles. Straubinger's taxane formulations include 1.5 to 8.0 mole percent of taxane. The composition is administered by various routes such as topical and parenteral routes. The dosage forms for parenteral administration includes solutions and suspensions and they can also be manufactured in the form of sterile solid compositions, which can be dissolved or suspended in sterile injectable medium immediately before use (abstract, col. 1, line 59 through col. 2, line 38; col. 7, line 48-51; col. 10, lines 20-68 and claims). It would have been obvious from Straubinger's teachings that one can have solutions or suspensions of taxanes in desired amounts in sealed containers and use them or prepare them from sealed containers just before use.

It would have been obvious to one of ordinary skill in the art to prepare Taxol formulations without cremophor if this excipient is not suitable for the human condition treated. One of ordinary skill in the art would be further motivated to use taxanes without this excipient since Straubinger teaches that cremophor when used as vehicle has been shown to cause fatal hypersensitivity episodes and therefore advocates alternate vehicles. To prepare the desired amounts of the formulations in sealed containers is well within the highly developed art of medical sciences, especially in view of Straubinger, which is suggestive of the use of taxane in the form of solutions or suspensions as such or prepare solutions or suspensions immediately before use. Alternately, to use Straubinger's taxane formulations in claimed amounts would have been obvious to one of ordinary skill in the art since Drug facts and comparisons shows that those amounts are routinely used in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK